REMARKS

Applicant has cancelled Claims 6-7, 13, 25 and 28-29. Claims 1-5, 8-12, 14-24, 26-27 and 30-34 are pending in this application.

The Examiner continued to reject claims 1-34 under 35 U.S.C. Section 102(b) as being anticipated by Mueller (US Patent No. 5725521). The Examiner also continued to reject claims 1-3, 6, 8, 9, 12 and 17-34 under 35 U.S.C. Section 102(b) as being anticipated by Kittrell (US Patent No. 5693043). Applicant respectfully traverses the rejections to the extent that they apply to the claims as amended.

For ease of understanding, Applicant will discuss the method claims (claims 27 and 30-34) first.

The present invention as claimed in method claim 27 will be explained, by way of example only, with reference to the figures in the present application. As seen in FIG. 12A and 12B, laser treatment of a blood vessel 115, such as laser treatment of varicose veins, involves the steps of (1) inserting an optical fiber through the blood vessel until the fiber tip 11 is appropriately positioned, (2) turning on a laser source and then slowly withdrawing the optical fiber (see paragraphs 79-82 of the present specification) while the laser is turned on. The laser energy is emitted at the exposed fiber tip 11 which then heats the blood in the vessel to create gas bubbles. The gas bubbles damage the inner wall of the vessel and ultimately cause the vessel to collapse.

In a conventional treatment device, the fiber tip may have direct contact with the inner vessel wall as shown in FIG. 12B for example. One problem is that it can result in vessel perforation because intense direct laser energy is delivered to the vessel wall rather than indirect thermal energy created as the blood is converted into gas bubbles. Laser energy in direct contact with the vessel wall may cause the vessel to perforate at the contact point and surrounding area. Blood escapes through these perforations into the perivascular tissue, resulting in post-treatment bruising and associated discomfort.

Another problem created by direct contact between the fiber tip and vessel inner wall is that inadequate energy may be delivered to non-contact segments of the diseased vessel. Inadequately heated vessel tissue may not collapse, resulting in incomplete closure of the vessel.

The present invention solves the above problems by incorporating a spacer element 19 such as shown in FIG. 13B. During a treatment operation, the optical fiber with the deployed spacer is slowly withdrawn while the laser is turned on. According to the invention, the

deployed spacer ensures that the fiber tip is positioned away from the inner wall of the blood vessel. Consequently, the spacer avoids the over heating or under heating of the inner vessel wall that occurs when the fiber tip comes in direct contact with the vessel.

Method claim 27 has been amended to more clearly recite this novel feature as "applying laser energy through the distal end of the optical fiber *while longitudinally moving the inserted optical fiber and spacer* such that the *spacer positions the distal end of the optical fiber away from the inner wall of the vessel* to prevent the distal end of the optical fiber from contacting the inner wall of the blood vessel". In other words, claim 27 calls for simultaneous application of laser energy and longitudinal movement of the optical fiber.

The Examiner states that Mueller discloses all of the steps of claim 27 without specifically pointing out which portions of Mueller disclose any of the recited steps of claim 27. Applicant respectfully submits that Mueller does not anticipate claim 27 for the following reasons.

Mueller teaches a transmyocardial revascularization (TRM) device for creating channels in the heart muscle using a laser device. In the Mueller device, the fiber tip is positioned outside of a blood vessel. As shown in FIG. 4 of Mueller, laser delivery device 84 is positioned through the endocardium surface 86 and into the myocardium tissue 90 which is not a blood vessel. Accordingly, Mueller does not teach the step of applying laser energy *while longitudinally moving the inserted optical fiber and spacer* as claimed in claim 27. The spacer of Mueller cannot perform that step because the fiber tip is not even inside the blood vessel in operation and accordingly cannot move longitudinally through the blood vessel while the laser is turned on.

The Examiner also stated that Kittrell discloses all of the steps of claim 27 without specifically pointing out which portions of Kittrell disclose any of the recited steps of claim 27. Applicant respectfully submits that Kittrell does not anticipate claim 27 for the following reasons.

Kittrell teaches an intravascular laser device for treatment of artherosclerotic disease by removing occlusive material or recanalizing an obstructed lumen. In other words, the Kittrell device, similar to the Mueller device, is also directed to opening an obstructed lumen. The spacer (176 as well as 146 and 166) of Kittrell refers to balloons positioned near the distal end of the treatment device. These balloons are used to rotate the optical fiber so as to move the position and direction of the laser beam to focus on the diseased tissue. Accordingly, Kittrell

does not teach the step of applying laser energy *while longitudinally moving the inserted optical fiber and spacer* as claimed in claim 27.

For the similar reasons as discussed above with respect to claim 27, Applicant submits that independent claim 31 is also patentable.

For device claims 1, 8, 22 and 26, Applicant has amended those claims to recite that the spacer is *directly attached* to or bonded to the bare optical fiber without any intervening element. Support for this feature, for example, is found in paragraphs 43 of the present specification. This direct attachment feature is advantageous because it allows the spacer to accommodate smaller diameter vessels. This feature is claimed in claim 1 as "a spacer *directly attached to an optical fiber* and arranged near a distal end of the optical fiber" (emphasis added).

By contrast, the spacer 70 of Mueller is attached to a tube 50 rather than the fiber 72 itself. In fact, the Mueller spacer is not even attached to the fiber as the fiber is slidable relative to the tube 50. Accordingly, the spacer of Mueller is not directly attached to the optical fiber as recited in claim 1.

In Kittrell, the balloon ("spacer") 176 is attached to a shield 12 and not to the optical fibers 20. At best, the balloon 176 is *indirectly* attached to the optical fibers 20 through the shield 12. Accordingly, the spacer of Mueller is also *not directly attached* to the optical fiber as recited in claim 1.

For the similar reasons as discussed above, independent claims 8, 22 and 26 are also patentable over Mueller and Kittrell either in combination or individually.

Applicant also submits that dependent claims 2-5, 9-12, 14-21, 23-24, 30 and 32-34 are patentable by virtue of their dependency from respective independent claims.

Based upon the above amendments and remarks, Applicant respectfully requests reconsideration of this application and its earlier allowance. Should the Examiner feel that a telephone conference with Applicant's attorney would expedite the prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

Harry K. Ahn
Reg. No. 40,243
REED SMITH LLP
599 Lexington Avenue
29th Floor
New York, NY 10022
Telephone No.: 212-521-5433
Attorney for Applicants

HKA